II. REMARKS

Formal Matters

Claims 1, 2, and 5-17 are pending after entry of the amendments set forth herein.

Claims 1-17 were examined and were rejected.

Claims 1, 13, 16, and 17 are amended. The amendments to claims 1, 13, 16, and 17 were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claims 1 and 17 is found in, e.g., claims 3 and 4 as originally filed. No new matter is added by these amendments. The amendments to claims 13 and 16 merely amend claim dependency. No new matter is added by these amendments.

Claims 3 and 4 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Rejections withdrawn

Applicants note with gratitude that the following rejections, raised in the previous Office Action, have been withdrawn: 1) rejection of claims 5 and 10 under 35 U.S.C.§112, second paragraph; 2) rejection of claims 1, 3, 4, 6, 7, and 10-17 under 35 U.S.C.§102(b) over Yang et al. ((1997) *Vaccine* 15:1303-1313); and 3) the rejection of claims 1-4 and 6-17 under 35 U.S.C.§103(a) over Yang et al. in view of McConkey et al. ((June 2003) *Nat. Medicine* 9:729-735).

Rejection under 35 U.S.C.§112, first paragraph

Claims 1-17 remain rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description.

The instant specification and claims comply with the written description requirement.

The instant specification, and thus the instant claims, are in compliance with the written description requirement of 35 U.S.C.§112, first paragraph. The instant specification describes an adequate number of nucleic acids encoding the recited MSP-1 protein. Furthermore, nucleic acids

encoding *P. falciparum* MSP-1 proteins, fragments, and muteins were known in the art as of the October 23, 2002 priority date of the instant application.

The instant application identifies GenBank sources of MSP-1 amino acid sequences. Substitute Specification, paragraph 0042. As discussed previously, the Federal Circuit has found that when the prior art includes the sequence information, precedent does not set a *per se* rule that the sequence information be provided afresh.

The instant application also incorporates by reference DE 19640817, which published as WO 98/14583 on April 9, 1998, and which discloses a number of *P. falciparum* MSP-1 sequences. See, e.g., U.S. Patent No. 6,933,130, which corresponds to WO 98/14583. Again, as mentioned above, and as discussed in detail previously, the Federal Circuit has found that when the prior art includes the sequence information, precedent does not set a *per se* rule that the sequence information be provided afresh.[1] Thus, as discussed previously, the Office should find, as did the Federal Circuit in *Capon* and in *Falkner*, that the specification satisfies the written description requirement of 35 U.S.C.§112, first paragraph for the claimed invention.

Nevertheless, and solely in the interest of expediting prosecution, claims 1 and 17 are amended as shown above.

Conclusion as to the rejection under 35 U.S.C.§112, first paragraph

Applicants submit that the rejection of claims 1-17 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

[1] *Capon v. Eshhar* (76 USPQ2d 1078 (CAFC 2005); and *Falkner v. Inglis* (79 USPQ2d 1001 (CAFC 2006).

Rejection under 35 U.S.C.§ 103 (a)

Claims 1-4 and 6-17 were rejected under 35 U.S.C.§ 103(a) as allegedly unpatentable over Yang et al. ((1997) *Vaccine* 15:1303-1313; "Yang") in view of Kumar et al (April, 2002) *Immunology Letters* 81:13-24).

The Office Action stated that the claimed invention and the teachings of Yang are described in the previous Office Action (mailed June 23, 2006). The June 23, 2006 Office Action stated that the "claimed invention wherein the recombinant MVA virus coding for *Plasmodium falciparum* MSP-1 protein is of the isolate 3D7 or FCB1 strain, wherein the signal peptide sequence controls the secretion of the gene product and the localization of the gene product relevant to the membrane"; and that Yang "does not teach the recombinant vaccinia virus MSP-1 protein is from the 3D7 or FCB1 isolate." June 23, 2006 Office Action, pages 8-9. The current Office Action stated that Kumar teaches a DNA plasmid vaccine encoding MSP-1 from the 3D7 strain of *P. falciparum*; and that Kumar teaches the contruction of a vaccinia recombinant expressing MSP-1.

The Office Action stated that it would have been obvious to use the 3D7 strain of Kumar. Applicants respectfully traverse the rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Yang does not teach each and every element of the instant invention as claimed. Yang neither discloses nor suggests a recombinant MVA virus comprising a nucleic acid encoding a *P. falciparum* MSP-1 protein. Yang discusses a recombinant vaccinia virus that comprises sequences encoding various C-terminal fragments of *P. falciparum* MSA1. Yang merely mentions MVA in the context of concerns regarding the safety of live vaccinia virus as a vaccine vector. In this context, Yang merely states that a "highly attenuated strain of vaccinia virus, Ankara (MVA), has been developed as an expression vector and shown to be equivalent to replication competent vaccinia virus in several vaccine models." Yang, page 1311, column 2, last paragraph.

Kumar does not cure the deficiency of Yang. Kumar neither discloses nor suggests a recombinant MVA virus comprising a nucleic acid encoding a *P. falciparum* MSP-1 protein. Kumar discusses a recombinant NYVAC (K1L) vaccinia virus that comprises sequences encoding a C-terminal 42 KD portion of an MSP-1 protein. Kumar, page 15, section 2.2. Thus, Kumar does not disclose a recombinant MVA virus comprising MSP-1-encoding nucleotide sequences.

The cited references neither disclose nor suggest all of the claim elements. As such, Yang, alone or in combination with Kumar, cannot render any of claims 1-4 or 6-17 obvious.

Conclusion as to the rejection under 35 U.S.C.§ 103 (a)

Applicants submit that the rejection of claims 1, 3, 4, 6, 7, and 10-17 under 35 U.S.C. §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number GRUE-004.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: April 9, 2007

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